In the United States Court of Federal Claims

No. 17-642V
(Filed: August 30, 2023)
(Reissued: September 20, 2023)*
FOR PUBLICATION

ELIZABETH DOLES,	*
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Petitioner,	*
	*
v.	*
	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*
	*

Benjamin Alexander Christian, mctlaw, Sarasota, FL, for Petitioner.

Catherine Elizabeth Stolar, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent, United States. With her on briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, *C. Salvatore D'Alessio*, Director, *Heather L. Pearlman*, Deputy Director, and *Darryl R. Wishard*, Assistant Director.

OPINION AND ORDER

Petitioner Elizabeth Doles, after experiencing neurological symptoms following two vaccinations, sought relief under the National Childhood Vaccine Injury Compensation Program. 42 U.S.C. §§ 300aa-10 to 34 ("Vaccine Act"). After the Special Master originally assigned to the case awarded damages, *see* Special Master's Ruling on Entitlement ("Ruling") at 1 (ECF 73); Special Master's First Decision Awarding Damages ("First Decision") at 2 (ECF 83), I granted the government's motion for review and remanded for additional proceedings, *see Doles v. Sec'y of Health & Hum. Servs.*, 159 Fed. Cl. 241 (2022) (*Doles I*). The original Special Master awarded damages a second time. *See* Special Master's Decision on Remand ("Second

* This Opinion was issued under seal on August 30, 2023. The parties were directed to propose redactions by September 13, 2023. No proposed redactions were submitted. The Court hereby releases publicly the Opinion and Order of August 30 in full.

Decision") at 2 (ECF 102). I granted the government's motion for review once more and reassigned to a different special master. *Doles v. Sec'y of Health & Hum. Servs.*, 163 Fed. Cl. 726 (*Doles II*), *reconsideration denied*, 163 Fed. Cl. 616 (2023). The new Special Master has found against Petitioner, *see* Special Master's Decision on Remand ("Third Decision") (ECF 129), who has filed a third motion for review.[1] I called for supplemental briefs, which the parties duly filed.[2] I deemed oral argument unnecessary. *See Young v. United States*, 94 Fed. Cl. 671, 675–76 (2010).

The motion for review is **DENIED**. The Special Master erred in several ways, but her decision to deny the petition is **SUSTAINED**.[3]

BACKGROUND

I. The Vaccine Act

To obtain compensation under the Vaccine Act, a petitioner must prove that a vaccine caused an injury. *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). There are two ways to show causation: (1) through "a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ('Table injury')," *id.* (citing 42 U.S.C. § 300aa-14(a)), or (2) by proof of causation in fact "where the complained-of injury is not listed in the Vaccine Injury Table ('off-Table injury')," *id.* (citing 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). For off-Table injuries, causation in fact has three elements: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.*

While some Vaccine Act petitioners claim novel injuries resulting from vaccines, others claim that an existing medical condition was "significantly aggravated" by a vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i)–(ii); *see Loving ex rel. Loving v. Sec'y of Dept. of Health & Hum. Servs.*, 86 Fed. Cl. 135, 143 (2009) ("[T]he Vaccine Act specifies that significant-aggravation and new-injury circumstances constitute separate avenues to potential recovery."). Petitioners in the latter category must prove three additional elements: "(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition

[1] *See* Mot. for Review of Decision on Remand ("Pet.'s Mot.") (ECF 132); Pet.'s Mem. in Supp. of Mot. for Review ("Pet.'s Brief") (ECF 132-1); *see also* Resp't's Resp. to Mot. for Review ("Resp't's Brief") (ECF 133).

[2] *See* May 18 Order (ECF 134); Pet.'s Supplemental Brief (ECF 135); Resp't's Supplemental Brief (ECF 136).

[3] This Court has jurisdiction. *See* 42 U.S.C. §§ 300aa-11(c), 300aa-16(a). Petitioner timely moved for review. *See* 42 U.S.C. § 300aa-12(e)(1).

following the vaccination if that is also pertinent), [and] (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination[.]" *Loving*, 86 Fed. Cl. at 144; *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). When a petitioner claims an aggravation, the *Loving* and *Althen* factors combine into a new composite test, with the *Althen* elements renumbered as parts four through six. *Loving*, 86 Fed. Cl. at 144**.**

A petitioner always must prove causation of off-Table injuries by preponderance of the evidence. *See, e.g.*, *Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1366 (Fed. Cir. 2012); *Althen*, 418 F.3d at 1278.[4] Although the petitioner's burden does not "require identification and proof of specific biological mechanisms," *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 549 (Fed. Cir. 1994), "a 'plausible' or 'possible' causal theory" is not enough, *see Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). Proof of causation requires "a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010); *Moberly*, 592 F.3d at 1322; *see also Knudsen*, 35 F.3d at 549 ("[C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [patient] without detailed medical and scientific exposition on the biological mechanisms."). A theory of causation must be supported by medical records or an expert's opinion. *Althen*, 418 F.3d at 1279 (citing 42 U.S.C. § 300aa-13(a)(1)).

II. Procedural and Factual History

The relevant facts and history of the case through the current remand are fully presented in my previous opinions. *Doles I*, 159 Fed. Cl. at 244–46; *Doles II*, 163 Fed. Cl. at 729–31. Briefly, Petitioner — a 67-year-old woman at the time of her vaccinations — alleged in her Amended Petition that she suffers from central nervous system ("CNS") demyelination "best characterized" as multiple sclerosis ("MS"). Am. Pet. ¶¶ 5–6 (ECF 44). She claimed that her vaccines "actually caused, or, alternatively, significantly aggravated" her condition. *Id.* at ¶ 10. She does not plead exactly when her symptoms began, but she went to the emergency room 44 days after her second vaccination for symptoms that began two nights before. *Id.* at ¶¶ 1–3; Ruling at 6; Third Decision at 29 n.14.

[4] The government can rebut proof of causation by showing, "also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 547 (Fed. Cir. 1994)); *see* 42 U.S.C § 300aa-13(a)(1)(B).

Because Petitioner's alleged injury does not appear on the Table for the relevant vaccines, 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a)(I), (II), (VI), (VII), she must prove causation rather than benefit from the statutory presumption. *Althen*, 418 F.3d at 1278. Central nervous system demyelination is a general term describing a number of medically distinct conditions — including MS, acute disseminated encephalomyelitis, and focal myelitis or transverse myelitis, among others, *see* Steel Rebuttal Report at 2 (ECF 57-2) — so Petitioner presented experts to explain her theory of injury in more detail.

The original Special Master's first ruling determined that Petitioner's MS had been significantly aggravated by her vaccines. Ruling at 19. The original Special Master's main support for that conclusion was a study by Langer-Gould *et al.*, which he interpreted as providing "evidence tending to show that vaccines did contribute to significantly aggravate subclinical autoimmunity into overt MS among the examined population." *See id.* at 24 n.11 (citing Annette Langer-Gould *et al.*, *Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 71 JAMA Neurol. 1506 (2014) ("Langer-Gould") (ECF 57-10)).

On review, I concluded that the original Special Master had misinterpreted Langer-Gould. *Doles I*, 159 Fed. Cl. at 247–49. Langer-Gould in fact found no association — in *any* patient population — between vaccinations and MS. *Id.* at 247. There was an association between vaccines and the broader universe of demyelinating conditions, but only for patients under age 50, and only within 14 days of the vaccine. *Id.* There was no association between vaccines and demyelinating conditions for patients 50 or older for any time period post-vaccination. *Id.* For patients younger than 50, the association between vaccinations and demyelinating conditions disappeared after 14 days. *Id.* As I put it originally:

> In short, Langer-Gould found no association between MS — the condition the Special Master identified as Petitioner's injury — and vaccinations. The only association found involved demyelinating conditions generally, *i.e.*, conditions *other* than the demyelinating condition Petitioner has. Even if there were an association between Petitioner's personal condition and vaccinations, it did not exist for patients in Petitioner's age group, only younger patients. And even if there were an association for her age group, the effect disappears soon after vaccination, such that there is no association between vaccinations and demyelinating conditions for *either* age group at the time the Special Master found Petitioner's symptoms in fact developed. [T]here is no way to look at the study's data and find an association between vaccinations and Petitioner's own condition.

Id. at 248. "Although there can be association without causation, there cannot be causation without association," so "a finding of causation would have to be *despite* the Langer-Gould study, not *because* of it." *Id.* Because the original Special Master had arbitrarily and capriciously misinterpreted Langer-Gould,[5] I remanded with instructions "to re-evaluate the medical evidence under the correct legal and scientific standards." *Id.* at 249.

On remand, the original Special Master contradicted aspects of his reasoning in the first ruling, and without explaining why — or even acknowledging — he had done so. *See Doles II*, 163 Fed. Cl. at 732 (comparing Ruling at 19–21 and Second Decision at 7, 21). Because that was arbitrary and capricious too, I vacated the Second Decision, remanded a second time, and ordered reassignment for a new special master to "review the record, order any necessary supplemental briefing from the parties, and issue a new entitlement decision[.]" *Id.* at 733. The matter was reassigned to the new Special Master, who accordingly issued the Third Decision.

The new Special Master concluded that "any consideration of Langer-Gould would be improper, based on the plain language in *Doles I*," and therefore did not include Langer-Gould in her consideration of "*Loving* prong four," *i.e.*, Petitioner's evidence of a medical theory of causation. Third Decision at 16, 16 n.11.

The new Special Master then evaluated the remaining record evidence, including Petitioner's medical records and the parties' expert reports and published literature. *Id.* at 24–29. She found that "Petitioner has not provided a sound and reliable medical or scientific explanation for how the vaccines she received could have significantly aggravated her MS." *Id.* at 28–29. The new Special Master therefore concluded that "Petitioner has not met her burden under *Loving* prong four/*Althen* prong one." *Id.* at 29; *see also id.* at 32 ("Based on the evidence presented in this case, and for the reasons discussed in this decision, I conclude that Petitioner has not demonstrated that the … vaccines can cause a significant aggravation of MS.").

The new Special Master did, however, explain how she would have interpreted Langer-Gould if she had believed she was permitted to do so on remand. Her reasoning was as follows, in full:

> The Langer-Gould authors found a statistically significant increased risk of CNS acute demyelinating syndrome onset in patients under the age of 50 within 30 days of vaccination. Langer-Gould at 1509-10. These findings indicate that susceptible individuals can have a CNS

[5] And had fallen short of the procedural standard of "fundamental fairness" by adopting his own theory of causation without notice to the parties. *Doles I*, 159 Fed. Cl. at 246–47; *see* RCFC App. B, Rule 8(b)(1).

> autoimmune disorder triggered by vaccination. Even though Petitioner was older than 50, and developed [her first episode of MS] 42 days after vaccination, I would have found this study still provides support for her causation theory. I note that Petitioner's presentation was somewhat unusual in that she did not have her first clinical manifestation of MS until she was 67 years old. As the McDonald Criteria note, MS typically presents between the ages of 20 and 50. Between 0 and 5% have onset at age 60 or older. Accordingly, finding a study sufficiently powered to detect a statistically significant increase in MS onset in patients older than 60 would likely prove difficult. Indeed, Langer-Gould noted as a limitation that "the number of older individuals was relatively small." [Langer-Gould] at 1512. Petitioner's burden under *Loving* prong four/*Althen* prong one is to provide a sound and reliable medical or scientific explanation for how the vaccines at issue caused the significant aggravation of her injury. The standard is not one of scientific certainty, "nor must the findings of the Court meet the standards of the laboratorian." *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991) (internal citation omitted). The study's broadly stated conclusion that "vaccines (like infections) may accelerate the transition from subclinical to overt autoimmunity in patients with existing disease" provides strong support for Petitioner's theory that the vaccines she received did just that. Langer-Gould at 1512. For those reasons, had I considered this study, I would have found that it, coupled with Fujinami, Frohman & Wingerchuk, and Petitioner's other evidence constitutes preponderant evidence in support of the fourth *Loving* prong.

Id. at 29 n.14 (some citations omitted).

Petitioner then moved for review.

DISCUSSION

Petitioner argues in the motion for review that the new Special Master could have considered the Langer-Gould study and erred by altogether refusing to do so. Pet.'s Brief at 4–5.[6] I entirely agree.

In *Doles I*, which related to the interpretation of Langer-Gould, I directed the original Special Master to "re-evaluate the medical evidence under the correct legal

[6] The government argues that Petitioner forfeited that argument by failing to raise it before. Resp't's Brief at 10–11. That demands too much from Petitioner. Petitioner could not have objected to *Doles I* on remand because the original and new Special Masters were bound by this Court's mandate. *Doles I*, 159 Fed. Cl. at 249; *see also Banks v. United States*, 741 F.3d 1268, 1276 (Fed. Cir. 2014) (discussing mandate rule). And she had no reason to object to *Doles I* in this Court after she prevailed on remand. Petitioner does not seem to have invited the new Special Master's error. *See* Tr. at 7–8 (ECF 128). Petitioner was therefore within her rights in raising the argument in response to the Third Decision.

and scientific standards." *Doles I*, 159 Fed. Cl. at 249. Then in *Doles II*, which ordered reassignment, I provided that the new Special Master was to "review the record" in issuing a new decision. *Doles II*, 163 Fed. Cl. at 733. Langer-Gould is unquestionably part of the "medical evidence" within the case's "record," so the remand instructions in both *Doles I* and *Doles II* expressly called for review of Langer-Gould — for whatever significance the study might have, consistent with the mandate. *See Contreras v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1363, 1369 (Fed. Cir. 2017) (special masters must follow this Court's instructions on remand); *see also* 42 U.S.C. § 300aa-12(e)(2)(C) ("[T]he United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter . . . remand the petition to the special master for further action *in accordance with the court's direction*.") (emphasis added).

The new Special Master understood that she had been directed "to consider the record anew," but for some reason thought that instruction did not include Langer-Gould, "any consideration [of which] would be improper." Third Decision at 16 & n.11. The new Special Master attributed the purported exception to the "plain language" of *Doles I*. *Id.* at 16 n.11. Yet the new Special Master cited no actual language requiring such an extreme position. Although *Doles I* showed how the original Special Master misinterpreted Langer-Gould, that hardly means that "any consideration" of the study was off the table. *Id.* On the contrary; the Special Masters only had to ensure that their consideration of the study complied with "the correct legal and scientific standards." *Doles I*, 159 Fed. Cl. at 249. The new Special Master thus misinterpreted the remand orders and performed an incomplete review of the record.[7]

The real question — addressed on my request in supplemental briefs — is whether the new Special Master's error prejudiced Petitioner. This Court and the

[7] Because *Doles I* and *Doles II* did not altogether forbid review of Langer-Gould, Petitioner's arguments about legal relevance and this Court's authority to exclude evidence presented to a special master are largely beside the point. *See* Pet.'s Brief at 4–17. I do not reach those arguments. Petitioner is plainly wrong, however, to the extent she argues that a special master's interpretation of Langer-Gould is beyond this Court's review. *See id.* at 15–19. Of course this Court can review interpretations of scientific studies: It is simply that the Court applies the deferential "arbitrary and capricious" standard when it does so. *See Boatmon*, 941 F.3d at 1358, 1362; *J. v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 20, 47 (2021) (special master's inaccurate interpretation of study was arbitrary and capricious); *see also Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1381 (Fed. Cir. 2021) (requiring this Court to ensure special masters have "drawn plausible inferences and articulated a rational basis for the decision") (quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)); *Greene v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 655, 665 (holding a special master's findings of fact arbitrary and capricious where the "accuracy" was in dispute "rather than just the weight he placed on the evidence"), *aff'd*, 841 F. App'x 195 (Fed. Cir. 2020); 42 U.S.C. § 300aa-12(e)(2) (granting this Court power to "set aside *any* of the findings of fact or conclusions of law of the special master found to be arbitrary, capricious, and abuse of discretion") (emphasis added).

Federal Circuit have ruled on a number of occasions that special master errors are not reversible unless the adverse party shows the error was prejudicial. *See, e.g.*, *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1343 (Fed. Cir. 2010) (finding special master's error harmless when "it did not affect the outcome of the proceeding"); *Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1526–27 (Fed. Cir. 1991) (finding error harmless "because it did not change the outcome of the case"); *see also A.Y. by J.Y. v. Sec'y of Health & Hum. Servs.*, 152 Fed. Cl. 588, 599 (2021); *Johnson v. Sec'y of Health and Hum. Servs.*, 33 Fed. Cl. 712, 728–29 (1995); *Cox v. Sec'y of Dept. of Health & Hum. Servs.*, 30 Fed. Cl. 136, 142–45 (1993). Here, the new Special Master helpfully explained why — if she had felt free to consider Langer-Gould — she would have concluded that it supported an award to Petitioner. Third Decision at 29 n.14.[8] I would of course revisit my *Doles I* analysis of Langer-Gould if the new Special Master provided persuasive reasons to do so. But had she found for Petitioner for the reasons she set out, her decision would have been arbitrary and capricious. I therefore conclude that her error in wholly disregarding the study could not have prejudiced Petitioner.

It is worth emphasizing at the outset that the new Special Master found Petitioner's other evidence insufficient to show causation. Third Decision at 28–29. Petitioner has not argued that the new Special Master erred in that respect, so objections to the new Special Master's treatment of the remaining evidence are forfeited. *See* RCFC App. B, Rule 24(b); *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 228 n.3 (2021). Given that forfeiture, as a matter of law none of Petitioner's other evidence — piecemeal or in any combination — is enough to show that her vaccinations caused her injuries. And because Petitioner has the burden to prove causation by a preponderance of the evidence, *see, e.g.*, *W.C.*, 704 F.3d at 1356, Petitioner can *only* show causation if Langer-Gould — the sole remaining piece of contested evidence — affirmatively supports it.

The new Special Master provided two reasons for interpreting Langer-Gould to support Petitioner's causation theory. I address them in turn.

First, the new Special Master noted that because onset of MS after age 50 is unusual, "finding a study sufficiently powered to detect a statistically significant increase in MS onset in patients older than 60 would likely prove difficult." Third

[8] For that reason, Petitioner is wrong to cite *Contreras*, 844 F.3d at 1368, for the proposition that "failure to consider relevant evidence is, in and of itself, harmful error." Pet.'s Supplemental Brief at 2. A petitioner is prejudiced when a special master ignores her medical theories and the evidence supporting them. *Contreras*, 844 F.3d at 1369. But because the new Special Master provided a proposed interpretation of Langer-Gould, this Court can consider whether her proposed interpretation would have changed the outcome of the case.

Decision at 29 n.14.[9] The new Special Master inferred on that basis that Langer-Gould's findings of a "statistically significant increased risk of CNS acute demyelinating syndrome onset in patients under the age of 50 within 30 days of vaccination" could be extended to Petitioner's MS. *Id.* There are several errors in that reading of Langer-Gould.

To begin with, treating Langer-Gould as evidencing causation for that reason violates the rules of formal logic — specifically, by committing a fallacy referred to as "denying the antecedent." *Cf. TorPharm, Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1329 & n.7 (Fed. Cir. 2003) ("An invalid argument of the general form: If p, then q. Not p. Therefore, not q."). I reasoned in *Doles I* that "[t]he fact that the Langer-Gould study shows no association relevant to [Petitioner] means that it does not evidence causation[.]" *Doles I*, 159 Fed. Cl. at 248. In other words: If no association, then no causation. But say, for argument, that the new Special Master is right that the lack of a statistical association in Langer-Gould between vaccinations and MS in older patients could be the result of lack of statistical power. That would call into question the premise that Langer-Gould shows no association between vaccinations and MS. But it cannot follow, logically, that Langer-Gould *does* show causation. It can only mean — as I pointed out in *Doles I* — that Langer-Gould does not *disprove* an association if there is other evidence to establish it. *Id.* The new Special Master, again, found that Petitioner's other evidence does not prove causation, so the Special Master's critique of Langer-Gould's statistical power does not help.

Now suppose instead that what the new Special Master *meant* to say was that because Langer-Gould shows an association between vaccines and demyelinating conditions for some demographics and post-vaccination timeframes, there is probably an association between vaccines and MS in Petitioner's demographic and timeframe, even though the study lacks statistical power to identify it. That reasoning is essentially identical to the mistaken interpretation of the original Special Master.

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[9] The new Special Master did not explain why she thought that Langer-Gould lacked statistical power sufficient to detect an association between vaccination and MS onset in patients older than 60. *See* Third Decision at 29 n.14; Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 254 (3d ed. 2011) ("Power is the chance that a statistical test will declare an effect when there is an effect to be declared."). But where Langer-Gould lacked statistical power, the investigators acknowledged it explicitly. Langer-Gould at 1512 (describing the study as "underpowered" with respect to "detecting associations with rare forms of CNS ADS (pediatric ADS and ADEM), uncommon exposures (single-antigen HepB vaccine), … small select subgroups (symptom onset within 180 days following HPV vaccine in young women)[, and] risk of CNS ADS following HepB vaccination in early childhood"). The investigators did not say that the study was underpowered as to older patients, only that "the number of older individuals was relatively small[.]" *Id.* The new Special Master's view that Langer-Gould was underpowered as to Petitioner's demographic is thus not only unexplained, but inconsistent with the investigators' own description of their study. Nonetheless, giving the new Special Master every possible benefit of the doubt, I shall assume *arguendo* that she was right.

The new Special Master overlooks the fact that Langer-Gould does not show an association between vaccines and MS for *anybody*: not in Petitioner's demographic, not in *any* demographic, and not within *any* time period after vaccination. *Id.* at 247. As noted in *Doles I*, the statistical association observed in Langer-Gould was between vaccinations and demyelinating conditions *other* than MS. *Id.* Statistical power has nothing to do with it, for Langer-Gould found no association between vaccines and MS even for demographics where statistical power is not in question.

Perhaps there are times when an association in one circumstance is enough to infer an association in another, notwithstanding statistical evidence to the contrary. To be minimally rational, though, such an inference must be grounded in evidence.[10] *See Germaine*, 155 Fed. Cl. at 227–28 (citing *Knudsen*, 35 F.3d at 549, and *Boatmon*, 941 F.3d at 1360). Why infer that a short-term association between vaccinations and non-MS demyelinating conditions in young patients can be generalized to MS, in older patients, longer after vaccination? The Special Master's discussion of Langer-Gould merely assumes the inference rather than explaining or justifying it. Third Decision at 29 n.14.

Whatever the outer limits might be on the new Special Master's discretion, she had to start from something, somewhere. Inferring that a vaccine can cause a given condition based solely on a study that does not show an association between vaccines and *that condition*, in circumstances like Petitioner's — only other conditions, in other circumstances — without any other evidence is arbitrary and capricious. *See, e.g.*, Olaf M. Dekkers, *The Long and Winding Road to Causality*, 34 European J. of Epidemiology 533 (2019) ("[T]he fundamental prerequisite before judging causality is the presence of an association. ... In short: no causation without association."); *see also Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1380 (Fed. Cir. 2015) ("Where, as here, a special master … makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law."); *Nussman v. Sec'y of Health & Hum. Servs.*, 83 Fed. Cl. 111, 120 (2008) (special master must explain rationale for decision); *Broekelschen*, 618 F.3d at 1345 (special master cannot find causation without "reputable medical or scientific explanation that pertains specifically to the petitioner's case").

[10] Imagine a study showing that University of Minnesota graduates — presumably because of a solid education and good work habits — enjoy heightened opportunities in employment generally, but not as pearl divers in Tahiti. No sensible person would infer that Golden Gophers probably also have advantages in pearl diving, whatever the sample sizes might be. The likelier conclusion would be that Tahitian pearl diving is a special situation where a University of Minnesota bachelor's degree has limited usefulness.

Second, the new Special Master pointed to Langer-Gould's "broadly stated conclusion that 'vaccines (like infections) may accelerate the transition from subclinical to overt autoimmunity in patients with existing disease,'" a conclusion the Special Master said "provides strong support for Petitioner's theory that the vaccines she received did just that." Third Decision at 29 n.14.

Assume — for a moment — that the new Special Master fairly characterized Langer-Gould's conclusions. Scientific studies have to be interpreted on their own terms *qua* scientific studies, just as courts treat other genres of written material. *See ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 420, 496–97 (2d. Cir 2013); *Partington v. Bugliosi*, 56 F.3d 1147, 1154–55 (9th Cir. 1995); *Ollman v. Evans*, 750 F.2d 970, 983–84 (D.C. Cir. 1984); *see also* Anya Bernstein, *Legal Corpus Linguistics and the Half-Empirical Attitude*, 106 Cornell L. Rev. 1397, 1439–40 (2021) (explaining that different categories of language should be read and interpreted in different ways). The real conclusions of a scientific study are found in its data, not in the accompanying verbiage. If the authors of a scientific study describe their findings in ways that the data do not support, the data control. *Cf. Jarvis v. Sec'y of Dept. of Health & Hum. Servs.*, 99 Fed. Cl. 47, 61 (2011) (holding, in the context of litigation experts, that scientific opinions need not be credited where "there is simply too great an analytical gap between the data and the opinion proffered") (citing *Cedillo*, 617 F.3d at 1339 (Fed. Cir. 2010) (itself citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997))). At a minimum, courts should avoid interpreting investigators' remarks in ways that contradict the study's actual findings. Here — at the risk of beating a dead horse — Langer-Gould found no association between vaccinations and MS, so it would be arbitrary and capricious to treat the investigators' words as showing such an association where the data do not.

Besides, the new Special Master misunderstood what the Langer-Gould investigators said about their findings. Here is the full paragraph containing the language she quoted:

> Findings from the present study show no long-term association of vaccines with an increased risk of MS and other CNS ADS. In younger patients, we observed a short-term increase in risk after vaccination of any type, which suggests that vaccines (like infections) may accelerate the transition from subclinical to overt autoimmunity in patients with existing disease. We found no association between HepB vaccination and an increased risk of MS or other CNS demyelination up to 3 years after vaccination, which is reassuring. Our results for HPV vaccine are inconclusive given the small number of cases and the paucity of previous studies on the topic. Our findings reconcile the anecdotal clinical reports of a CNS ADS onset shortly after vaccination with the larger body of

> epidemiologic literature showing no long-term increased risk of MS or other forms of CNS ADS following vaccination. Our findings do not warrant any change in vaccine policy.

Langer-Gould at 1512.

In context, the "broadly stated conclusion" the new Special Master relied upon turns out to be a mirage. Third Decision at 29 n.14. The language she quoted was in fact limited to "short-term" effects in "younger patients," rather than broadly generalizable, and does not mention MS. Langer-Gould at 1512. The investigators recited that they found "no long-term association of vaccines with an increased risk of MS[.]" *Id.* They also said that while their data were consistent with "anecdotal clinical reports of a CNS ADS onset shortly after vaccination," the data also corroborated "the larger body of epidemiologic literature showing no long-term increased risk of MS or other forms of CNS ADS following vaccination." *Id.* All of this is consistent with the underlying data, as analyzed in *Doles I*: There might be an association between vaccinations and non-MS demyelinating conditions soon after vaccination in younger patients, but there is no evidence of one with MS, in older patients, later post-vaccination.

The new Special Master was of course correct that the standard in vaccine cases "is not one of scientific certainty, 'nor must the findings of the Court meet the standards of the laboratorian.'" Third Decision at 29 n.14 (quoting *Bunting*, 931 F.2d at 873). The Vaccine Act does not require a diagnosis of a petitioner's condition or certain proof of its etiology. But where a study cannot rationally be read to support a petitioner's theory of causation, it would be arbitrary and capricious to do so. Because the new Special Master's interpretation of Langer-Gould would have been arbitrary and capricious, her erroneous exclusion of the study from her analysis was harmless.

CONCLUSION

For the foregoing reasons, Petitioner's motion for review is **DENIED**. The decision of the new Special Master is **SUSTAINED**.

The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Stephen S. Schwartz
STEPHEN S. SCHWARTZ
Judge